PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference AP102151/KIR	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/FI2005/050046	International filing date *(day/month/year)* 22.02.2005	Priority date *(day/month/year)* 27.02.2004
International Patent Classification (IPC) or national classification and IPC INV. C01B33/00		
Applicant DELSITECH OY		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 9 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *sent to the applicant and to the International Bureau)* a total of 9 sheets, as follows:
      ☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☒	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
09.09.2005	31.05.2006
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized officer Rigondaud, B Telephone No. +31 70 340-2327

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/FI2005/050046

Box No. I Basis of the report

1. With regard to the **language**, this report is based on

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3(a) and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4(a))
   - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages	
1-33	as originally filed
Claims, Numbers	
1-37	received on 24.03.2006 with letter of 22.03.2006
Drawings, Sheets	
1/4-4/4	as originally filed

   ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 2-37

because:

☒ the said international application, or the said claims Nos. 36,37 relate to the following subject matter which does not require an international preliminary examination *(specify)*:

see separate sheet

☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 2-37 are so unclear that no meaningful opinion could be formed *(specify)*:

see separate sheet

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed *(specify)*.

☒ no international search report has been established for the said claims Nos. 2-37

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13*ter*.1(a) or (b) and 13*ter*.2.

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions, and such tables were not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1
	No:	Claims	
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1
Industrial applicability (IA)	Yes:	Claims	1
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item I

Basis of the report

1- The amendments to the claim 2 fulfill the requirements of Article 34(2)(b) PCT.

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1- The subject-matter of claims 2-37 does not fulfil the requirements of Article 6 PCT.

2- The Applicant has argued that claim 2 merely defines two alternatives of preparing a sol-gel derived SiO2 with a desired bioresorption rate:

- a first alternative to be used if a very fast bioresorption rate is desired and corresponding to a silica according to claim 1

- a second alternative involving first correlating changes defined with bioresorption rates resulting from these changes

and that a method with changes correlating with the desired slower biodegradation rate is carried out for obtaining the sol-gel derived SiO2 with said desired biodegradation rate.

On the one hand, the requirement that a claim should be clear applies to individual claim. Therefore the meaning of the terms of a claim should, as a far as possible, be clear for the person skilled in the art from the wording of the claim alone (see PCT Guidelines, 5.31).

On the other hand, Rule 6.3 PCT defines the manner of claiming. More precisely, Rule 6.3(b)(ii) stresses that the characterizing portion preceded by the words inter alia "characterized in that" states the technical features which it is desired to protect.

The Examiner is of the opinion that claim 2 is still not clear and does not fulfil both this requirement and Rule 6 PCT for the following reasons:

- the subject-matter of claim 2 concerns a method for adjusting the bioresorption rate of a sol-gel derived SiO2, the characterizing part of which contains inter alia:

(i) a reference to a product obtainable by a process of another claim (page 35, lines 15 and 16)

(ii) a reference to a method for preparing SiO2 (page 36, lines 8-10)

Those remarks cast real doubts on the scope of claim 2, and consequently on dependent claims 3 to 37.

3- Additionaly, claims 36 and 37 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

D1: WO 97/45367 A (ORION-YHTYMAE OY; BIOXID OY; AHOLA, MANJA; FAGERHOLM, HEIDI; KANGASNIE) 4 December 1997 (1997-12-04)

D2: WO 96/03117 A (THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA) 8 February 1996 (1996-02-08)

D3: RAO A VENKATESWARA ET AL: "Effect of gel parameters on monolithicity and density of silica aerogels" J MATER SCI; JOURNAL OF MATERIALS SCIENCE JUN 1 1993, vol. 28, no. 11, 1 June 1993 (1993-06-01), pages 3021-3026, XP002359192

D4: ASOMOZA M ET AL: "Calorimetric study of the sol-gel silica gelation stage: Effect of gelation pH" MATERIALS LETTERS, NORTH HOLLAND PUBLISHING COMPANY. AMSTERDAM, NL, vol. 33, no. 3-4, December 1997 (1997-12), pages 153-160, XP004336616 ISSN: 0167-577X

D5: POPE E J A ET AL: "SOL-GEL PROCESSING OF SILICA II. THE ROLE OF THE CATALYST" JOURNAL OF NON-CRYSTALLINE SOLIDS, NORTH-HOLLAND PHYSICS PUBLISHING. AMSTERDAM, NL, vol. 87, no. 1/2, 11

October 1986 (1986-10-11), pages 185-198, XP001031064 ISSN: 0022-3093

1- For the assessment of the present claims 36 and 37 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

2- The lack of clarity (see Re Item VIII) notwithstanding, the subject-matter of claim 1 does not involve an inventive step in the sense of Article 33(3) PCT, and therefore the criteria of Article 33(1) PCT are not met.

Observation: It is not clear from the application that it makes "possible to vary the bioresorption rate to a great extent independent of whether the structure is dense or porous". This argument was not retained for the following reasonning.

Biodegrable sol-gel derived silica products as carriers for controlled delivery of biologically active agents are known from the prior art.

The document **D1**, cited in the present application as well, is regarded as being the closest prior art to the subject-matter of claim 1, and insofar as this claim can be understood, this document shows the following features thereof:

- a controllably dissolvable silica xerogel can be prepared by allowing silica-alkoxide, such as tetraethylorthosilicate (TEOS), to react with water and optionally a solvent, e.g. ethanol or polyethylene glycol, or a combination of solvents, at low temperature, preferably at room temperature, in the presence of an acidic, e.g. acetic acid, or a basic catalyst by hydrolyzation and polycondensation (see D1, page 7, lines 9 to 16).
- the silica xerogel can be obtained in the form of a monolith, a coating, a particle of small diameter or a fiber. Depending on the form, either gelation is allowed to be performed before evaporation of the solvent, or gelation of the sol and evaporation of the solvent occur simultaneously by a spray-drying method or a fiber spinning method (see D1, page 7, lines 17-24).

- the silica-xerogel dissolves controllably, and the release rate of the biologically active agent from the silica-xerogel, based on this dissolution, can be controlled via processing parameters of the gelation conditions (see D1, page 5, line 31 to page 6, line 1)
- examples 2 and 3 of D1 are particularly relevant. TEOS, water and ethanol ratios, and temperature fulfil conditions of claim 1 of the present invention, pH of the sol being not mentioned.

Moreover, D1 points out that dissolution behaviour of xerogels depends on several parameters. Drying temperature has an influence on the dissolution rate of the material (see D1, page 8, lines 8-10). D1 reports that other parameters that control the polycondensation reaction, such as TEOS:H2O molar ratio, pH of the silica sol and ageing have a minor influence on dissolution behaviour of gels. Nevertheless, D1 suggests that variations around those parameters influence in a certain way the dissolution of the final product.

Moreover, **D2** points out as well the great versatility of the sol-gel process (see D2, page 15, lines 14-32).

Versatile possibilities of sol-gel technology, based on hydrolyzation of silicon alkoxyde and subsequent gelation by using acid or base as catalyst are reported as well in **D3-D5**, in which reactions are modified by changing the following parameters:
- type of silicon alkoxide,
- alkoxide/water ratio
- amount of solvent (alcohol)
- pH of the sol

Hence, varying the pH parameter of the sol-gel method disclosed in **D1** to pH=2, as proposed in claim 1 and thereby arriving at a process of claim 1, is merely one of several straightforward possibilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill, in order to solve the problem posed.

Therefore, the subject-matter of **claim 1** does not involve an inventive step (Article 33(3) PCT).

Re Item VIII

Certain observations on the international application

1- The subject-matter of claim 1 is not clear because:

1-1 the term "very fast bioresorption rate" is vague and indefinite in scope. For the purpose of examination, this feature was not considered as being limiting.

1-2 the term " a change or changes of sol composition are induced" is vague as well, leading to uncertainty in the scope of the subject-matter embraced by the embodiment of point b) ii) of claim 1. This statement has no technical content and is vague as exemplified in the application page 12, lines 12-26, inter alia by *"any other component needed to obtain a desired property of the final SiO2"*.

Therefore, the term " a change or changes of sol composition are induced" cats doubts on the scope of claim 1 which does not clearly define in such a case the matter for which protection is sought.
This point was therefore not considered to be limiting for the purpose of examination.

CLAIMS

1. A method for preparing a sol-gel derived SiO_2 monolith, preferably with a minimum diameter of ≥ 0.5 mm, coating, preferably with a thickness of < 0.5 mm, or particle, preferably with a maximum diameter of ≤ 100 µm, with a very fast bioresorption rate, said SiO_2 optionally comprising a specific percentage or percentages of a biologically active agent or agents other than the SiO_2 itself with or without protective agent or agents for said biologically active agent or agents, wherein method a sol-gel derived SiO_2 is prepared from a sol comprising water, an alkoxide or inorganic silicate and a lower alcohol, i.e. an alcohol with ≤ 4 carbons, using a mineral acid or a base as a catalyst, preferably a mineral acid, and said sol is aged and dried **characterised** in that

a) in the sol the starting

i) pH is from 0.05 to 2.5, preferably 1.5 to 2.5, most preferably 2.0,

ii) molar ratio of water to the alkoxide or inorganic silicate is 0.5 to 2.5; preferably 1.5 to 2.5,

iii) molar ratio of alcohol to the alkoxide or inorganic silicate is ≥ 0.5, preferably ≥ 1.0; and

b) either,

i) the sol is, without induced changes of sol composition,

- let to gel spontaneously at a temperature of ≤ 25 °C or an elevated temperature of 65 °C to 90 °C , preferably at an elevated temperature of 65 °C to 90 °C, or
- gelation of the sol is done by forced drying of the sol, or

ii) a change or changes of sol composition are induced after sol ageing but before gel formation, said change or changes of sol composition optionally comprising addition of said biologically active agent or agents with or without said protective agent or agents, and

the ratio t/t_{gel} is ≥ 0.005, preferably ≥ 0.1, most preferably ≥ 0.9, wherein

t is the ageing time of the sol, i.e. time from preparation of said sol to the induced changes, and

t_{gel} is the time point where the sol would have turned to a gel without the induced changes; and

forced drying of the sol is carried out or initiated within a time of ≤ 30 minutes, preferably ≤ 15 minutes, most preferably ≤ 5 minutes, from said induced change or changes.

2. A method for adjusting the bioresorption rate of sol-gel derived SiO_2 monolith, preferably with a minimum diameter of ≥ 0.5 mm, coating, preferably with a thickness of < 0.5 mm, or particle, preferably with a maximum diameter of ≤ 100 µm, optionally comprising a specific percentage or percentages of a biologically active agent or agents other than the SiO_2 itself with or without protective agent or agents for said biologically active agent or agents, **characterised** in that

A) a SiO_2 with a very fast bioresorption rate is obtained according to the method of preparing a SiO_2 of claim 1; and

B) a SiO_2 with a slower bioresorption rate than the very fast bioresorption rate is obtained by correlating a desired biodegradability of a SiO_2 with changes a), b) and/or c) to the method of preparing a SiO_2 according to claim 1, wherein

a) comprises deviating in the sol any of the starting values:

i) pH,

ii) molar ratio of water to the alkoxide or inorganic silicate, and/or

iii) molar ratio of alcohol to the alkoxide or inorganic silicate;

from the values defined in a) i) – iii) of claim 1;

b) comprises carrying out induced changes by addition of a component or components, including optional addition of the biologically active agent or agents with or without said protective

agent or agents, said changes affecting any of the values i) – iii) of a) of claim 1 or a) if applied by

i) not carrying out forced drying, or

ii) carrying out or initiating forced drying of the sol later than defined in b) ii) of claim 1; and

c) comprises deviating the temperature for letting the sol gel spontaneously from the values defined in b) i) of claim 1; and

a method for preparing the SiO_2 with said changes to the method correlating with the desired biodegradability is carried out for obtaining the SiO_2 with the desired slower biodegradability.

3. The method according to claim 2 **characterised** in that an alkoxide, preferably tetraethoxysilane (TEOS), is used for preparing the sol-gel derived SiO_2.

4. The method according to claim 2 or 3 **characterised** in that that an inorganic silicate, preferably sodium or potassium silicate, is used for preparing the sol-gel derived SiO_2.

5. The method according to any of claims 2 to 4 **characterised** in that the lower alcohol is ethanol.

6. The method according to any of claims 2 to 5 **characterised** in that the induced change is selected from the group consisting of adding water, adding the alkoxide or inorganic silicate, adding the alcohol, adjusting pH by adding an acid or base, preferably the acid or base used as the catalyst, adding the optional bioactive agent or agents with or without protective agent or agents for said biologically active agent or agents affecting any of the values i) – iii) of a) in claim 1 or a) of claim 2 if applied, and any combination thereof.

7. The method according to any of claims 2 to 6 **characterised** in that drying of the sol is drying by ambient heat, vacuum drying, electromagnetic drying,

acoustic drying, spray-drying or freeze-drying, preferably spray-drying or freeze-drying.

8. The method according to any of claims 2 to 7 **characterised** in that forced drying of the sol is carried out, preferably by spray-drying or freeze-drying.

9. The method according to claim 8 **characterised** in that forced drying is freeze-drying initiated by freezing the sol.

10. The method according to claim 8 or 9 **characterised** in that the temperature of the sol is ≤ +90 °C, preferably ≤ +50 °C, most preferably ≤ +40 °C.

11. The method according to any of claims 2 to 10 **characterised** in that the gel is dried.

12. The method according to claim 11 **characterised** in that drying of the gel is drying by ambient heat, vacuum drying, electromagnetic drying, acoustic drying, spray-drying or freeze-drying, preferably ambient heat or freeze-drying.

13. The method according to claim 11 or 12 **characterised** in that the gel is dried at a temperature of ≤ 700 °C, preferably ≤ 50 °C, and most preferably ≤ 40 °C.

14. The method according to any of claims 2 to 13 **characterised** in that a value to be deviated to obtain a slower bioresorption rate is the ratio of water to the alkoxide or inorganic silicate, and the more the ratio of water to alkoxide or inorganic silicate is deviated to be higher or lower the slower the bioresorption rate obtained.

15. The method according to any of claims 2 to 14 **characterised** in that a value to be deviated to obtain a slower bioresorption rate is the ratio of alcohol to

the alkoxide or inorganic silicate, and the more the ratio is deviated to be higher or lower the slower the bioresorption rate obtained.

16. The method according to any of claims 2 to 15 **characterised** in that a value to be deviated to obtain a slower bioresorption rate is the pH, and the more the pH is deviated to be higher or lower the slower the bioresorption rate obtained.

17. The method according to any of claims 2 to 16 **characterised** in that a biologically active agent or agents is added to the sol before gel formation.

18. The method according to any of claims 2 to 17 **characterised** in that any of the values pH, molar ratio of water to the alkoxide or inorganic silicate, and/or molar ratio of alcohol to the alkoxide or inorganic silicate is changed to deviate from the ranges defined in claim 1, a) i) – iii), after sol ageing but before gel formation and/or optional addition of said biologically active agent or agents, and within ≤ 30 minutes, preferably ≤ 15 minutes and most preferably ≤ 5 minutes from the change forced drying of the sol is carried out or initiated.

19. The method according to any of claims 2 to 18 **characterised** in that the biologically active agent or agents is selected from the group consisting of a drug, peptide, protein, hormone, growth factor, enzyme, polysaccharide, living or dead cells or viruses or parts thereof, plasmids, polynucleotides, water soluble ions, salts and any combination thereof.

20. A bioresorbable sol-gel derived SiO_2, obtainable according to the method of any of claims 2 to 19, **characterised** in that

a) the SiO_2 is a monolith, preferably with a minimum diameter of ≥ 0.5 mm,

b) the SiO_2 comprises no biologically active agent other than the SiO_2 itself, and

c) the dissolution rate of the SiO_2 in a TRIS buffer at a temperature of +37 °C and pH 7.4 is ≥ 0.04 wt-%/h, preferably ≥ 0.07 wt-%/h and more preferably ≥ 0.15 wt-%/h.

21. A bioresorbable sol-gel derived SiO_2, obtainable according to the method of any of claims 2 to 19, **characterised** in that

a) the SiO_2 is a monolith, preferably with a minimum diameter of ≥ 0.5 mm,

b) the SiO_2 comprises at least one biologically active agent other than the SiO_2 itself, and

c) the dissolution rate of the SiO_2 in a TRIS buffer at a temperature of +37 °C and pH 7.4 is ≥ 0.35 wt-%/h.

22. A bioresorbable sol-gel derived SiO_2, obtainable according to the method of any of claims 2 to 19, **characterised** in that

a) the SiO_2 is a coating, preferably with a thickness of < 0.5 mm,

b) the SiO_2 comprises no biologically active agent other than the SiO_2 itself, and

c) the dissolution rate of the SiO_2 in TRIS buffer at a temperature of +37 °C and pH 7.4 is ≥ 0.04 wt-%/h, preferably ≥ 0.07 wt-%/h and more preferably ≥ 0.15 wt-%/h.

23. A bioresorbable sol-gel derived SiO_2, obtainable according to the method of any of claims 2 to 19, **characterised** in that

a) the SiO_2 is a coating, preferably with a thickness of < 0.5 mm,

b) the SiO_2 comprises at least one biologically active agent other than the SiO_2 itself, and

c) the dissolution rate of the SiO_2 in TRIS buffer at a temperature of +37 °C and pH 7.4 is ≥ 0.04 wt-%/h, preferably ≥ 0.07 wt-%/h and more preferably ≥ 0.15 wt-%/h.

24. A bioresorbable sol-gel derived SiO_2, obtainable according to the method of any of claims 2 to 19 **characterised** in that

a) the SiO_2 is a particle, preferably with a maximum diameter of ≤ 100 µm,

b) the SiO_2 comprises no biologically active agent other than the SiO_2 itself, and

c) the dissolution rate of the SiO_2 in TRIS buffer at a temperature of +37 °C and pH 7.4 is ≥ 0.04 wt-%/h, preferably ≥ 0.07 wt-%/h and more preferably ≥ 0.15 wt-%/h.

25. A bioresorbable sol-gel derived SiO_2, obtainable according to the method of any of claims 2 to 19 **characterised** in that

a) the SiO_2 is a particle, preferably with a maximum diameter of ≤ 100 µm,

b) the SiO_2 comprises at least one biologically active agent other than the SiO_2 itself, and

c) the dissolution rate of the SiO_2 in TRIS buffer at a temperature of +37 °C and pH 7.4 is ≥ 0.5 wt-%/h.

26. The SiO_2 according to any of claims 20, 22, 23 and 24, **characterised** in that the dissolution rate of the SiO_2 is ≥ 0.30 wt-%/h.

27. The SiO_2 according to claim 21 or 26, **characterised** in that the dissolution rate of the SiO_2 is ≥ 0.5 wt-%/h preferably ≥ 1.0 wt-%/h, more preferably ≥ 2.0 wt-%/h and most preferably ≥ 4.0 wt-%/h.

28. A bioresorbable sol-gel derivedSiO_2, obtainable according to the method of any of claims 2 to 19, **characterised** in that

a) the SiO_2 is a monolith, preferably with a minimum diameter of ≥ 0.5 mm,

b) the SiO_2 comprises no biologically active agent other than the SiO_2 itself, and

c) the dissolution rate of the SiO_2 in a TRIS buffer at a temperature of +37 °C and pH 7.4 is from 0.001 to 0.15 wt-%/h, preferably from 0.002 to 0.07 wt-%/h, and more preferably from 0.006 to 0.05 wt-%/h.

29. A bioresorbable sol-gel derived SiO_2, obtainable according to the method of any of claims 2 to 19, **characterised** in that

a) the SiO_2 is a monolith, preferably with a minimum diameter of ≥ 0.5 mm,

b) the SiO_2 comprises at least one biologically active agent other than the SiO_2 itself, and

c) the dissolution rate of the SiO_2 in a TRIS buffer at a temperature of +37 °C and pH 7.4 is from 0.001 to 0.06 wt-%/h, preferably from 0.002 to 0.05 wt-%/h, and from 0.006 to 0.025 wt-%/h.

30. The SiO_2 according to claim 22 or 23 **characterised** in that the dissolution rate of the SiO_2 in TRIS buffer at a temperature of +37 °C and pH 7.4 is from 0.001 to 0.15 wt-%/h, preferably from 0.002 to 0.07 wt-%/h, and more preferably from 0.006 to 0.05 wt-%/h.

31. A bioresorbable sol-gel derived SiO_2, obtainable according to the method of any of claims 2 to 19 **characterised** in that

a) the SiO_2 is a particle, preferably with a maximum diameter of ≤ 100 µm,

b) the SiO_2 comprises no biologically active agent other than the SiO_2 itself, and

c) the dissolution rate of the SiO_2 in TRIS buffer at a temperature of +37 °C and pH 7.4 is from 0.001 to 0.008, and preferably from 0.002 to 0.003 wt-%/h.

32. A bioresorbable sol-gel derived SiO_2, obtainable according to the method of any of claims 2 to 19 **characterised** in that

a) the SiO_2 is a particle, preferably with a maximum diameter of ≤ 100 µm,

b) the SiO_2 comprises at least one biologically active agent other than the SiO_2 itself, and

c) the dissolution rate of the SiO_2 in TRIS buffer at a temperature of +37 °C and pH 7.4 is from 0.001 to 0.10 wt-%/h, preferably from 0.002 to 0.07 wt-%/h, and more preferably from 0.006 to 0.05 wt-%/h.

33. A bioresorbable sol-gel derived SiO_2 monolith, preferably with a minimum diameter of ≥ 0.5 mm, coating, preferably with a thickness of < 0.5 mm, or particle, preferably with a maximum diameter of ≤ 100 µm, obtainable according to the

method of any of claims 2 to 19, wherein said SiO_2 comprises a biologically active agent other than the SiO_2 itself and said biologically active agent is a peptide, protein or cell, **characterised** in that the dissolution rate of the SiO_2 in TRIS buffer at a temperature of +37 °C and pH 7.4 is ≥ 0.04 wt-%/h, preferably ≥ 0.07 wt-%/h and more preferably ≥ 0.15 wt-%/h.

34. A bioresorbable sol-gel derived SiO_2 monolith, preferably with a minimum diameter of ≥ 0.5 mm, coating, preferably with a thickness of < 0.5 mm, or particle, preferably with a maximum diameter of ≤ 100 µm, obtainable according to the method of any of claims 2 to 19, wherein said SiO_2 comprises a biologically active agent other than the SiO_2 itself and said biologically active agent is a peptide, protein or cell, **characterised** in that the dissolution rate of the SiO_2 is ≥ 0.5 wt-%/h and preferably ≥ 4.0 wt-%/h.

35. A bioresorbable sol-gel derived SiO_2 monolith, preferably with a minimum diameter of ≥ 0.5 mm, coating, preferably with a thickness of < 0.5 mm, or particle, preferably with a maximum diameter of ≤ 100 µm, obtainable according to the method of any of claims 2 to 19, wherein said SiO_2 comprises a biologically active agent other than the SiO_2 itself and said biologically active agent is a peptide, protein or cell, **characterised** in that the dissolution rate of the SiO_2 in TRIS buffer at a temperature of +37 °C and pH 7.4 is from 0.001 to 0.15 wt-%/h, preferably from 0.002 to 0.07 wt-%/h, and more preferably from 0.006 to 0.05 wt-%/h.

36. Use of a bioresorbable sol-gel derived SiO_2 according to any of claims 20 to 35 for administering a biologically active agent to a human or animal body, wherein said use comprises administering selected from the group consisting of oral, buccal, rectal, parenteral, pulmonary, nasal, ocular, intrauterine, vaginal, urethral, topical, transdermal and surgically implantable administering.

37. Use of a bioresorbable sol-gel derived SiO_2 according to any of claims 20 to 35 for administering a biologically active agent to a plant.